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10/807,369

03/24/2004

Tatsuya Yanagawa

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EXAMINER

WRIGHT, PATRICIA KATHRYN

ART UNIT

PAPER NUMBER

1743

MAIL DATE

DELIVERY MODE

07/23/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/807,369

Applicant(s)

YANAGAWA, TATSUYA

Examiner

P. Kathryn Wright

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) 8 and 9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 March 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>3/24/2004</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-7, drawn to an automatic analyzer apparatus, classified in class 422, subclass 67.
 - II. Claims 8-9, drawn to an automatic analyzer apparatus, classified in class 422, subclass 64.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are directed to related inventions (i.e., automatic analysis apparatus). The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j).

In the instant case, the inventions as claimed can have a materially different design, mode of operation, function, or effect. Specifically, the apparatus of group I has a read device which calculates the analysis result based on pre-obtained analytical information corresponding to the reagent lot and adds a caution mark to the analysis result to attract attention when the reagent lot information is not read out successfully. Conversely, the apparatus of group II has a read device which reads the reagent type information designated to disregard the reagent lot and to calculate processing for

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determining the analysis result based on pre-obtained analytical information irrespective of the condition when the reagent lot information was read. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

3. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

4. During a telephone conversation with Susan Pan on July 6, 2007 a provisional election was made without traverse to prosecute the invention of group I, claims 1-7. Affirmation of this election must be made by applicant in replying to this Office action. Claims 8-9 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Drawings

5. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "error handling function" in claims 1, 2 and 5, and the "re-calculation function" in claims 3 and 6 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

6. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate

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prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

7. A series of singular dependent claims is permissible in which a dependent claim refers to a preceding claim which, in turn, refers to another preceding claim.

A claim which depends from a dependent claim should not be separated by any claim which does not also depend from said dependent claim. It should be kept in mind that a dependent claim may refer to any preceding independent claim. In general, applicant's sequence will not be changed. See MPEP § 608.01(n). Claims 3 and 4 depend from claim 1. These claims are separated by independent claim 2 .

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.

Claims 1, 2 and 5 recite method steps within claims drawn to an apparatus. Specifically, the aforementioned claims recite an analysis apparatus which has an "error handling function" to perform the process of calculating the analysis result based on pre-obtained analytical information corresponding to the reagent lot and the process of adding a caution mark to the analysis result to attract attention. It unclear what further *structural limitations* are added to the apparatus by the error handling function.

Furthermore claims 1,2 and 5 recite "add the a caution mark". This should be changed to --add a caution mark--. Correction is required.

Claims 3 and 6 recite "a re-calculation function" to perform the process of re-calculating the analysis result when the normal reagent lot information is input to correct the analysis result to which the calculation mark was added. It unclear what further *structural limitations* added to the apparatus by the re-calculation function.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 1-3, 5 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Saito et al. (EP 0 562 425 A1), hereinafter "Saito".

Saito teaches an analysis apparatus 2 for spotting a sample on the dry analysis element (analysis slide 10 and slide package) and analyzing the sample for its composition by measurement and calculation based on analytical information corresponding to the element information. The analysis apparatus of Saito comprises a reading device (bar code reading means and magnetic code reading means) for reading out element information attached to a dry analysis element (col. 10, lines 46+). The element information attached to the analysis element includes at least reagent lot information for correcting reagent-lot-specific variations (see col. 7, lines 5-40) to produce a lost specific standard curve.

Furthermore, the analysis apparatus of Saito has an error handling function (processing program) to calculate the analysis result based on pre-obtained analytical

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information (fixed information; col. 7, lines 14+) corresponding to the reagent lot and add a caution mark (alarm signal; see col. 10, lines 26) to attract attention when the reagent lot information is not read out successfully (i.e., different reagent lot information is used).

With respect to claims 3 and 6, Saito teaches a re-calculation function to re-calculate the analysis result when normal reagent lot information is input to correct the analysis result to which the caution mark was added. That is, the assay device of Saito can produce a lot-specific standard curve.

12. Claims 1-3, 5 and 6 are rejected under 35 U.S.C. 102(e) as being anticipated by Hiramatsu et al. (US 2004/0086429), hereinafter "Hiramatsu".

Hiramatsu teaches an analysis apparatus for spotting a sample on the dry analysis element (test piece) and analyzing the sample for its composition by measurement and calculation based on analytical information corresponding to the element information. The analysis apparatus of Hiramatsu comprises a reading device 8 for reading out element information attached to a dry analysis element (col. 10, lines 46+). The element information 32 attached to the analysis element includes at least reagent lot information for correcting reagent-lot-specific variations, see para. [0060].

Furthermore, the analysis apparatus of Hiramatsu also has an error handling function (processing program) to calculate the analysis result based on pre-obtained analytical information corresponding to the reagent lot and add a caution mark (warning message; see para. [0107]) to attract attention when the reagent lot information is not read out successfully (i.e., measurement is past expiration date).

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With respect to claims 3 and 6, Hiramatsu teaches a re-calculation function to re-calculate the analysis result when normal reagent lot information is input to correct the analysis result to which the caution mark was added.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

15. Claims 4 and 7 rejected under 35 U.S.C. 103(a) as being unpatentable over Saito (EP 0 562 425 A1) or Hiramatsu (US 2004/0086429), in view of Lappe (US Patent No. 5,902,982).

The teachings of Saito and Hirmatus have been summarized previously, *supra*. Saito and Hirmatus teach the element information in the form of a bar code, not an array pattern of dots.

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Lappe discloses an assay card having a machine readable assaying indicia located on a surface of the card. Lappe discloses the assay card 10 may be provided by a substrate 20 having assaying indicia 32a (bar code) and 32b (dot array pattern), see lines 1-67, col. 4, figs. 1-4C. Lappe further discloses that the appearance of the indicia of the present invention, including identification code or assaying indicia, may be provided in many contemplated optical forms. These forms include other patterns that are optically very different in appearance to those illustrated in FIGS. 2A, 3A, and 3B (lines 24-36, col. 7).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the claimed invention to utilize on the assay device of Saito or Hirmatus the indicia in the form of a dot array pattern, as taught by Lappe, in order to provide information to a suitable apparatus which is not "human readable"; thus, not subject to interpretation and possible unauthorized dissemination (see col. 1, lines 19+ of Lappe).

Conclusion

16. No claims allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Wright whose telephone number is 571-272-2374. The examiner can normally be reached on Monday thru Thursday, 9 AM to 6 PM, EST.


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

July 17, 2007

pkw


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